REMARKS

Time for Response

Initially, it is noted that the Examiner's objection to the informal drawings set a two month period of time to submit new drawings in compliance with 37 CFR § 1.81. (Paper No. 20070801 at 2). The Office Action Summary, however, set a three month shortened statutory period for response. As there was a problem with Examiner Stroud's telephone, the prior attorney handling this matter, Stephen Brown, spoke with Supervisory Examiner Gartenberg who stated that the deadline for filing the response (the three month shortened statutory period) is the controlling due date, and that accordingly, we need not separately comply with the two month deadline set for filing the corrected drawings. Examiner Gartenberg said that we should indicate in this response that the three month shortened statutory period applies to the entirety of the Office Action including the objection to the drawings.

Accordingly, it is submitted that the three month extension petition and fee for reply with this response provides a timely response to Paper No. 20070801.

Objection to the Drawings

As noted above, the Examiner has objected to the drawings as not of sufficient quality to permit examination. (Id.). The Examiner required replacement drawings in accordance with 37 CFR § 1.81. (Id.).

As required by the Examiner, we provide replacement drawing sheets of good quality from the scanned images to permit examination. Each of the four sheets is

labeled "Replacement Sheet" in the page header, as requested by the Examiner. Also, the original text at the bottom of page 3 is deleted, as it is included verbatim within paragraph 25 of the specification.

Applicants submit that the filing of the replacement drawing sheets is timely, as noted above under the section labeled "Time for Response". Withdrawal of the objection to the drawings is requested.

Amendments

Claims 1-6 have been cancelled without prejudice.

Claim 7 is amended to recite "[a] method for treating a patient suffering from bone destruction, the method comprising the step of inserting at the site of bone destruction a bone graft composite, wherein said bone graft composite replaces diseased bone at the site of bone destruction ***and comprises a bisphosphonate***." The amendment obtains support from the specification at, for example, paragraph 10, and original claim 9.

Claim 9 is cancelled without prejudice, as incorporation of its subject matter into amended claim 7 renders claim 9 redundant. Claim 10 is amended to depend from claim 7 rather than claim 9 in view of the cancellation of claim 9. Support is found in the specification at, for example, paragraph 10, and in original claims 9 and 10.

New claims 11-19 are added. Support for new claim 11 and new claim 12 is found in the specification, for example, in paragraphs 10, 20, and 21.

New claim 13 recites that the "bone destruction is mediated by osteoclasts." Support is found throughout the specification, for example, paragraph 3, lines 1-3, paragraph 5, paragraph 6, paragraph 8, lines 6-8 and lines 16-18, paragraph 9, paragraph 22, lines 11-14, and paragraph 26, lines 1-3.

New claim 14 recites that the bone destruction results from a disease selected from those listed. Support is found at paragraph 7, lines 2-4.

New claim 15 is an independent claim which recites, "[a] method of inhibiting the activity or formation of osteoclasts at the site of insertion of a bone graft composite in a subject having bone destruction mediated by osteoclasts, comprising inserting the bone graft composite in the subject such that it replaces diseased bone at the site of bone destruction and wherein the bone graft composite comprises a bisphosphonate". Support is found throughout the specification, for example, paragraph 3, lines 1-3, paragraph 5, paragraph 6, paragraph 8, lines 6-8 and lines 16-18, paragraph 9, paragraph 22, lines 11-14, paragraph 26, lines 1-3, and original claims 7 and 9.

New claims 16-19 are supported in the specification such as the support noted above for new claim 15 and, for example, by original claims 8 and 10-12.

See In re Gardner, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l). No new matter is added by the present amendments. Entry and consideration of the amendments is requested.

Anticipation Rejections

Claims 1-5[1] were rejected under 35 U.S.C. § 102(b) as anticipated by Long et al., U.S. Patent No. 6,630,153 ("Long"), as disclosed and claimed. (Paper No. 20070801 at 2). In making the rejection, the Examiner asserted that "Long teaches a bone graft composite comprising a carrier material, and Pamidronate . . . " (Id. at 3).

We note that claims 1-6 have been cancelled. Accordingly, the rejection based upon Long has been rendered moot. Withdrawal of the rejection is respectfully requested.

Claims 1-10 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,080,779 to Gasper et al., ("Gasper"). (Id.)

For the reasons set forth below, the rejection respectfully is traversed.

[1] The Examiner may have intended to reject claims 1-**6** based upon Long, and made a typing error in reciting claims 1-5. Applicants reserve the right to present claim 6 again if the Examiner did not intend to reject claim 6. Clarification is requested.

Gasper discloses "methods and compositions for stimulating the growth of skeletal (bone) tissue, which methods and compositions use, as at least one of the active ingredients, a compound of [formula 1 or 2]." Col. 3, ln. 63-67 – Col. 4, ln. 29. Included among the genus of formula 1 and 2 compounds of Gasper are compounds that are known to "behave as antihypercholesterolemic agents" such as lovastatin. Col. 17, ln. 10-14. Col. 17, ln. 39-41; Figure 1. Gasper further discloses that "the invention is directed to methods to treat bone disorders by directly stimulating bone formation using the compounds described and to pharmaceutical compositions for this use." Col. 4, ln. 30-34. Gasper discloses that "[i]n another aspect, the invention is directed to methods to treat bone disorders by administering the above compounds of formulas 1 or 2 in combination with additional compounds and materials that complement their effects. These additional materials include small molecules that enhance bone formation or inhibit resorption such as ... bisphosphonates which are ... known for [inhibiting bone resorption]." Col. 4, ln. 35-44.

In making the rejection, the Examiner asserted that Gasper "teaches a compound to be implanted at a bone defect site containing a carrier and Pamdronate [sic]." (Id. at 3). The Examiner also asserted that "Gasper further teaches a method comprising the step of inserting at the site of bone destruction a bone graft composite, wherein said bone graft composite replaces diseased bone at the site of bone destruction" and that "representative uses of compounds and combinations ... included ... repair of bone defects and deficiencies... 'can also be useful in repair ... or surgical resection of bone (for instance, for cancer treatment', the insertion step is preceded by

surgical removal of the diseased bone implicit in the phrase 'surgical resection'." (Id.) The Examiner further asserted that the "bone graft composite" of Gasper "comprises Pamidronate..." (Id.)

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.,* 221 USPQ 481, 485 (Fed. Cir 1984).

Initially, we note that claims 1-6 and 9 are deleted. For this reason alone, the rejection should be withdrawn as to these claims.

In addition, claims have been amended and new claims added, as noted above. We note that independent amended claim 7 recites "[a] method for treating a patient suffering from bone destruction, the method comprising the step of inserting at the site of bone destruction a bone graft composite, wherein said bone graft composite replaces diseased bone at the site of bone destruction ***and comprises a bisphosphonate***." Original claim 8, amended claim 10, and new claims 11-14 depend from amended claim 7.

New independent claim 15 recites "[a] method of inhibiting the activity or formation of osteoclasts at the site of insertion of a bone graft composite in a subject having bone destruction mediated by osteoclasts, comprising inserting the bone graft composite in the subject such that it replaces diseased bone at the site of bone

destruction and wherein the bone graft composite comprises a bisphosphonate. New claims 16-19 depend therefrom.

Furthermore, in a §102(b) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). "Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is disclosed in the applied reference." *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990). The Examiner is required to point to the disclosure in the reference "***by page and line***" upon which the claim allegedly reads. *Chiong v. Roland*, 17 USPQ2d 1541, 1543 (BPAI 1990).

The rejection fails to identify where in Gasper each and every element of amended claim 7 (having the subject matter of original claims 7 and 9), and of dependent claims 8 and 10 is shown. What the rejection states, including, *inter alia*, that "Gasper teaches a ***compound*** to be implanted at a bone defect site containing a carrier and Pamdronate [sic]", is insufficient as a matter of law to support a conclusion of anticipation, and for this additional reason, the rejection should be withdrawn. (Paper No. 20070801 at 3) (emphasis added).

Moreover, there is a "burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103. . . ." *In re Warner*, 154 USPQ 173, 177 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). The rejection fails to provide any basis, let alone the requisite factual basis to sustain a rejection for anticipation. Thus, for this reason also, the rejection should be withdrawn.

It is submitted that the Examiner has mischaracterized and misapplied Gasper. Gasper teaches that a compound of formula 1 or formula 2 such as the anticholesterolemic agent lovastatin be used in the disclosed method for stimulating the growth of skeletal (bone) tissue. ***Gasper does not even require the presence of either (i) a bisphosphonate, or (ii) an implantable device***. To reiterate, Gasper discloses simply the use of a compound of formula 1 or formula 2 to promote bone formation. Abstract. And, promoting bone formation is ***the*** stated purpose, according to Gasper.

The present invention, on the other hand, does not require the use of a compound of formula 1 or formula 2 or any anticholesterolemic agent, for that matter. The present claims recite methods that, unlike Gasper, require the use of a bone graft composite. The present invention is not concerned, as is Gasper, with the singular purpose of stimulating the growth of skeletal tissue. Objects of the present invention include, rather, inhibiting the activity of osteoclasts and preventing bone resorption. Specification, paragraph 9.

For each of these reasons alone, Gasper lacks "identity of invention" with the present claims, and the rejection should fall.

Where Gasper discloses the use of "additional compounds" to those of the genus of formula 1 and formula 2 compounds, it is to "complement [the] effects" of the formula 1 and formula 2 compounds. Col. 4, lines 37-38. Gasper discloses that one of the numerous possible types of "additional compounds" that can be used with a compound of formula 1 or formula 2 in connection with promoting bone formation is a bisphosphonate. Entire reference, e.g., Abstract, last three lines. ***Thus, where Gasper***

provides for the use of a bisphosphonate, it is only in combination with a compound of formula 1 or 2. The claims of the present application, on the other hand, do not recite such a combination. Furthermore, even in Gasper's combination of a compound of formula 1 or formula 2 with a bisphosphonate, there is, again, no requirement for the use of an implantable device.

Where the Examiner cites the "representative uses of the compounds and combinations", Gasper Col. 5, line 59, the Examiner's citation spanning Col. 5, ln. 38 through Col. 6, line 14 (Paper No. 20070801 at 3), the "compounds" mentioned are compounds of formulas 1 and 2. Regarding the "combinations" mentioned, Gasper again teaches the use of a compound of formula 1 or 2 optionally in combination with another agent (such as a bisphosphonate).

The Examiner's analysis is entirely improper. The Examiner picked and choosed various phrases from Gasper and strung them together piecemeal in a manner that gives the impression that Gasper has the particular disclosure that the Examiner asserts that it does. The parsing together of select phrases of the Examiner's choosing in this manner does not reflect the reality of Gasper's actual disclosure.

In the portion of Gasper cited by the Examiner spanning Col.5, lines 38 through Col. 6, line 14, nowhere is there a disclosure of a method for treating a patient suffering from bone destruction, the method comprising the step of inserting at the site of bone destruction a bone graft composite, wherein said bone graft composite replaces diseased bone at the site of bone destruction and comprises a bisphosphonate. The portion of Gasper cited by the Examiner pertaining to "cancer treatment" actually reads,

"[t]he compounds and combinations of the present invention can also be useful in repair of congenital, trauma-induced or surgical resection of bone (for instance, for cancer treatment), and in cosmetic surgery." Col. 6, lines 7-10. Gasper thus discloses that a compound of formula 1 or 2, alone or in combination with another agent (such as a bisphosphonate), may be used at the site of damaged bone to "repair", i.e., stimulate new bone growth. There is no disclosure of inserting a bone graft composite comprising a bisphosphonate at this site of bone destruction. The Examiner has improperly "read in" that "the insertion step is preceded by surgical removal of the diseased bone implicit in the phrase 'surgical resection'". Surgical resection refers to surgical removal of part of an organ or structure. The Examiner has failed to identify how "surgical resection" encompasses a next step of inserting any implantable device, nonetheless the bone graft composite of the present invention.

The Examiner has not shown that each and every element of the claims is present in Gasper. Accordingly, the rejection is rendered moot.

We further observe that as disclosed in Example 7 of Gasper at Col. 26, bisphosphonates alone and bisphosphonates with simvastatin were tested *in vitro* to determine their effect on stimulation of bone formation. The bisphosphonate pamidronate "gave negligible effects" on increase in bone formation. Col. 26, lines 29-30. In view of the disclosure of Gasper, one skilled in the art would understand that pamidronate is not a favored bisphosphonate of Gasper for the stated purpose of promoting bone formation.

Applicants also submit that it would be improper to apply the present rejection to any of the new claims.

Reconsideration and withdrawal of the rejection is requested.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on February 8, 2008.

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Respectfully submitted,

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